

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : A. SAIKAWA et al.  
Serial No. :  
Filed on :  
Title : Sustained-Release Composition, Method of Its  
Production and Use Thereof  
Attn: Box PCT

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, 1.97 and 1.98, applicants request consideration of (X) the references listed on the attached Form PTO-1449 and/or (X) the additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed.<sup>1</sup>

1. This Information Disclosure Statement is submitted:

- a. (X) within 3 months of the filing date of the above-identified application, or  
( ) within 3 months of entry into the national phase of the International Application, or ( ) before the mailing date of the first Office Action on the merits, and thus no certification and/or fee is required.
- b. ( ) after the events of above paragraph 1-a and prior to the mailing date of a final Office Action or Notice of Allowance, and thus:
  - ( ) the certification of paragraph 2 below is provided, or
  - ( ) a fee of \$240.00 is enclosed (37 CFR 1.17(p)).
- c. ( ) after the mailing date of a final Office Action or a Notice of Allowance and prior to payment of the issue fee, and thus the certification of paragraph 2 below is provided and a petition and fee of \$130.00 are enclosed (37 CFR 1.17(i)).

2. It is hereby certified that:

- ( ) each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- ( ) no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart

<sup>1</sup> A copy is not provided for each reference previously cited by or submitted to the Patent Office in prior parent application Serial No. \_\_\_\_\_.

foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Statement.

3. (X) Consideration of the following additional information (including any co-pending or abandoned U.S. application, prior uses and/or sales, etc.) is requested:

Pending U.S. application corresponding to the Ref. No. A2 listed on the Form PTO-1449: Serial No. 08/849,172

4. For each non-English language reference listed on the attached Form PTO-1449:

- ( ) reference is made to an English language translation submitted herewith, and/or
- ( ) reference is made to a foreign patent office search report (in the English language) submitted herewith, and/or
- ( ) reference is made to an English language translation of a foreign patent office search report submitted herewith, and/or
- ( ) reference is made to the concise explanation contained in the specification of the present application at page(s), and/or
- ( ) reference is made to the concise explanation attached thereto and/or
- ( ) reference is made to the concise explanation set forth below:

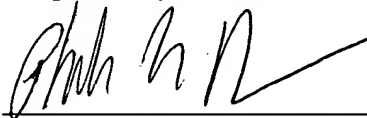
5. ( ) Applicants also offer the following comments for the Examiner's consideration:

6. (X) Also enclosed is a copy of: (X) the International Search Report citing these references, ( ) the International Preliminary Examination Report, and ( ) the Written Opinion.

Applicants respectfully request that the listed documents be considered by the Examiner and formally be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP 9609.

Date: June 29, 2000

Respectfully submitted,



Philippe Y. Riesen, Reg. No. 35,657  
Attorney for Applicants  
c/o Takeda Pharmaceuticals America, Inc.  
Patent Office  
1745 Jefferson Davis Highway, Suite 408  
Arlington, VA 22202-3425  
Phone #: (703) 416-5160  
Fax #: (703) 416-5163  
Customer No. 23,115